REMARKS

Claims 1-15 are currently pending in this application. In response to the Office Action mailed June 21, 2002 (the "Office Action"), Applicants have elected to prosecute the invention of Class I (claims 1-15) and, as part of this affirmation, cancelled claims 16-20 from prosecution. Claims 1-15 have been amended to overcome the rejections set forth in Paragraphs 4-7 of the Office Action. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

I. Claims

A. Restriction

In Paragraph 1 of the Office Action, a Restriction Requirement was set forth calling for an election between Invention I (claims 1-15) and Invention II (claims 16-20). Further to the provisional election referenced in Paragraph 2 of the Office Action, Applicants hereby affirm the provisional election of Invention I (claims 1-15) and, as part of this election, have cancelled claims 16-20 from prosecution.

B. 35 USC 112, 2nd Paragraph

In Paragraph 5 of the Office Action, Claim 1 was rejected under 35 USC 112, 2nd

Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, Claim 1 was deemed indefinite because "dispersion phase" was recited without specifying the medium in which the titanium particles are dispersed.

Claim 1 has been amended to clarify that the "dispersion phase" is disposed at least partially within the polymeric matrix. Applicants respectfully submit that claim 1, as amended, particularly points out and distinctly claims the subject matter which applicants regard as the invention. As such, the rejection under 35 USC 112, 2nd Paragraph should be withdrawn.

C. 35 USC 103(a) – Mannschedel in view of Shoher et al.

In Paragraph 7 of the Office Action, Claims 1-15 were rejected as being unpatentable over US Pat. No. 6,126,446 to Mannschedel ("Mannschedel") in view of U.S. Pat. No. 5,272,184 to Shoher et al. ("Shoher"). Applicants respectfully traverse this rejection as follows.

Independent claim 1, as amended, recites a composition for filling a void in an orthopedic joint or between bone separations. The composition comprises a polymeric matrix selected from a group consisting of gutta percha, balata, and polyisoprene, and any mixtures thereof. The composition further includes a dispersion phase disposed at least partially within the polymeric matrix, wherein the dispersion phase comprises titanium particles less than 50 microns in size. The composition has a resilient, non-dispersing state at or below body temperature, and is heatable to a fluid state above body temperature, such that the composition may be injected into the void while in the fluid state, thereafter returning to the resilient, non-dispersing state.

Independent claim 11, as amended, recites a composition for filling a void of an orthopedic joint or between bone separations, the composition having a resilient, non-dispersing state at body temperature, and heatable to a fluid state for injection into the void. The composition comprises a polymeric matrix selected from a group consisting of gutta percha,

balata, and polyisoprene, and any mixtures thereof. The composition also includes titanium particles less than 50 microns in size, wherein the titanium particles comprise between 1 and 50 percent by weight of the composition. The composition has a resilient, non-dispersing state at or below body temperature, and heatable to a fluid state above body temperature, such that the composition may be injected into the void while in the fluid state, thereafter returning to the resilient, non-dispersing state.

Neither the Mannschedel nor Shoher references, alone or in combination, appear to disclose or suggest the features of amended Claims 1 or 11. Among other voids, these references appear to be completely silent regarding the claimed feature of providing a composition comprising a polymeric matrix having a *fluid state* due to heating above body temperature and a *resilient, non-dispersing state* due to cooling to body temperature, nor the claimed feature of injecting the composition *while in the fluid state.* While Mannschedel does disclose a composition including gutta percha, the gutta percha is provided as a <u>powder</u> which is *not* provided having a fluid state above body temperature and a resilient, non-dispersing state upon cooling to body temperature. Instead, the gutta percha powder is simply combined with a sealer and thereafter introduced into the root canal. Given this void, it necessarily follows that the gutta percha of Mannschedel is not injected the *while in the fluid state* (above body temperature), as set forth in amended claims 1 or 11.

Nor does the Shoher reference disclose or suggest these features. While Shoher does disclose the use of metals such as titanium for filling a dental cavity, it nonetheless teaches away from any combination with a flowable composition such as the polymeric matrix of the present

invention. The metallic composition of Shoher is first introduced into the dental cavity while in a "putty-like" form such that it will "readily assume the geometry of the cavity (8) with minimal pressure." (Col. 4, lines 45-47). There is no teaching whatsoever that the putty-like metallic composition is heated prior to introduction. The metallic composition (in putty form and non-elevated temperature) is then removed from the dental cavity and *thereafter* heat-treated to form a porous metal structure (Col. 4, lines 66-67). This heat-treating occurs outside the dental cavity. Only after this heat-treating can the dental implant of Shoher be re-introduced into the dental cavity (Col. 6, lines 47-50).

The thermopolymer composition of the present invention, on the other hand, is specifically introduced into a void while in the fluid state due to being heated above body temperature. Shoher appears to be completely silent regarding any such teaching. This is a significant distinction in that the process of Shoher will necessarily take a considerable amount of time to fill a dental cavity with the metallic composite, based on the need to initially fit the dental cavity, remove the composite, heat the composite to provide a metal structure, and reintroduce the structure into the dental cavity. The thermopolymer composition of the present invention, on the other hand, is capable of quickly and easily filling voids by raising the temperature until it assumes a flowable fluid state, injecting it into the particular void to be filled, and allowing it to cool such that it can assume a resilient, non-dispersing form within the void.

Based on the foregoing, Applicants respectfully submit that the Mannschedel and Shoher references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set

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forth in amended claims 1 and 11. It is respectfully requested that the rejection in Paragraph 7 of

the Office Action be withdrawn. Claims 1 and 11 are believed to be in proper condition for

allowance and an indication of such is hereby respectfully requested.

Claims 2-10 and 12-15, being dependent upon and further limiting independent claims 1

and 11, respectively, should be allowable for the reasons set forth in support of the allowability

of claims 1 and 11, as well as the additional limitations they contain.

CONCLUSION

Reconsideration and allowance of the claims in this application is respectfully requested.

In the event that there are any questions concerning the remarks above or the application in

general, the Examiner is cordially invited to telephone the undersigned attorney so that

prosecution may be expedited.

Respectfully submitted,

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 $\mathbf{R}_{\mathbf{W}}$

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